NiliMEDIX
Innovative Medicine

510(K) SUMMARY

JUN - 6 2008

510(k) Number K070844

Applicant's Name: NiliMedix Ltd.
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Contact Person: Yoram Levy, Qsite
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Binyamina, Israel 30500
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Trade Name: ***ADI Insulin Pump***

Classification: **Name**: External infusion insulin pump
Product Code: LZG
Regulation No: 880.5725
Class: II
Classification Panel: 80 - General Hospital and Personal Use Device

Device Description:

The NiliMedix ***ADI Insulin Pump*** is an ambulatory, battery operated, rate programmable micro infusion pump, designed for continuous delivery of insulin. A custom reservoir is driven by the insulin pressure to deliver preset basal profiles and patient programmed bolus of insulin through FDA cleared infusion sets into subcutaneous tissue. The ADI pump is restricted to sale by, or on the order of a physician.

Intended Use Statement:

The NiliMedix ADI insulin pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Predicate Device: Substantial equivalence to the following predicate device is claimed:

Minimed Model 508	Ambulatory Insulin Pump	K990801	Decision Date: June 8, 1999

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Performance Standards

The performance standard that is applicable to the testing of infusion pumps is IEC60601-2-24.

The ADI complies with the European Medical Device Directive 93/42/EEC (Annex II) and with the voluntary standards ISO 13485, ISO 10993, IEC 60601-1, IEC 60601-1-2, CISPR 11, IEC 61000-4-2/3/4/5, IEC 55011 and IEC 801-2.

Summary of non-clinical performance data

The ADI Insulin Infusion Pump has been designed and tested in accordance with IEC 60601-2-24.
The following tests were conducted:

Pump Flow rate Accuracy, Pump Bolus Accuracy, Battery Indication Performance, Air In System Detection, Valve leakage and Piston Leakage Alarm , Valve blockage Alarm, Cartridge depletion and Low insulin Alert, Usability study, Cartridge Performance validation, Pump Operational Life validation, Infusion set testing for compatibility with ADI insulin pump, Flow Rate Accuracy for Minimum Flow Rate, Flow Rate Accuracy after Change in the infusion rate or Bolus Dose, Insulin Stability Study, Spring Component validation, Minimum Bolus Accuracy, Occlusion Alarm Test, Free fall Test and Vibration tests.

The ADI pump was also tested for biocompatibility, sterilization validation, electrical safety and EMC according to the relevant standards.

Performance tests were conducted in order to show that the quality of the design is as good as the predicate device and meets the standard's requirements.
The performance tests show that the ADI performance is substantially equivalent to the predicate device

Summary of Clinical performance data

Due to the satisfactory results of the comprehensive bench performance tests, clinical study of predicate devices and the long use of predicate devices, NiliMedix believes that animal and clinical studies are not required to determine the safety and efficacy of the device.

Conclusions:

Evidence of equivalence has been demonstrated that:

- The NiliMedix ADI intended use and indications for use were previously cleared by FDA for the predicate device.

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- Performance tests demonstrate that the ***ADI Insulin Pump*** is as safe and effective as the predicate for its intended use
- Safety and performance testing were implemented and found that the ***ADI Insulin Pump*** performs safe and effective.

Therefore, we believe that the ADI is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NiliMedix Limited
C/O Mr. Yoram Levy
Qsite
31 Haavoda Street
Binyamina
ISRAEL 30500

JUN - 6 2008

Re: K070844
Trade/Device Name: ADI
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: May 18, 2008
Received: May 23, 2008

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

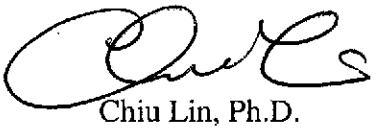
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NiliMEDIX

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070844

Device Name: ADI

Indications for Use: The NiliMedix ADI insulin pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
510(k) Number

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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